IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

NOTICE OF CONTINUATION OF ORAL DEPOSITION
OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-S

TO: Defendants ETHICON, INC., Johnson & Johnson, Inc., (hereinafter "Defendants") and their Attorneys of Record

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants' corporate designee regarding TVT-S to begin on June 04, 2013, at 9:00 a.m., at the offices of Riker Danzig at One Speedwell Avenue in Morristown, New Jersey. The witness shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day to day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. R. Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device

industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR. Civ. P. 26.2(c)(7).

2. "Defendants", "Ethicon, Inc.", "Johnson & Johnson Inc.", "you" or "your" refers to, without limitation, Ethicon, Inc., and Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR. Civ. P. 26.2(c)(2); *see also* Fed. R. Civ. P. 34(a).

4. "TVT-S" means the TVT-Secur device cleared by the FDA on or about November 28, 2005 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

5. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT-S to the present.

This 22nd day of May, 2013.

PLAINTIFFS' CO-LEAD COUNSEL

By: ____/s/Thomas P. Cartmell_____
THOMAS P. CARTMELL
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1100
Fax 816-531-2372
tcartmell@wcllp.com

D. RENEE BAGGETT
Aylstock, Witkin, Kreis and Overholtz, PLC
17 E. Main Street, Suite 200
Pensacola, FL 32563
850-202-1010
850-916-7449
Rbaggett@awkolaw.com
Plaintiffs' Co-Lead Counsel

EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge of and shall be able to testify concerning the following subject matters related to "TVT-S" defined in Paragraph 4 of Notice of Deposition:

I. DESIGN AND DEVELOPMENT OF MESH PRODCUTS

a. The Standard Operating Procedures (SOP) associated with design and development of TVT-S;

b. The complete design history file for TVT-S, including each component part of the file, the custodian responsible for the file and the maintenance of the file;

c. Members and procedures of the Product Development Team for TVT-S;

d. The Operating Procedures associated with Product Development Cycle;

e. The Design Output file, including the specifications of the TVT-S;

f. The user needs and design requirements for the TVT-S;

g. The Cadaver Lab evaluations for the TVT-S;

h. The specifics of all testing related to the TVT-S during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, and leaching;

i. All project names of the TVT-S;

j. Design verification of the TVT-S;

k. Design validation of the TVT-S;

l. The Design Review, Process Qualification (PQ) and Design Transfer for the TVT-S;

m. The Product Device Design Safety Assessment (DDSA) and the policies and procedures related to these analyses;

n. Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA);

o. The Product Device Design Requirements Matrix;

p. The Product Device Qualitative and Quantitative Characteristics Worksheets, including but not limited to Hazard Worksheet and ranking tables;

q. The Clinical Validation Test Reports;Procedures for preparing and keeping Minutes and Agendas for Design Review Meetings;

r. As it relates to design control and validation, any and all discussions or documents related to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your TVT-S;

s. Any patents related to the TVT-S and its predecessor mesh products.

t. The identity of and financial compensation paid to any consultants retained during the design and development of the TVT-S;

u. The monitoring, investigation and evaluation of post-marketing adverse event reports for your TVT-S for design issues;

v. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your TVT-S for design issues;

w. As it relates to design control and validation, the investigation, evaluation and determination as to whether there is an association between the design of TVT-S and any adverse event experienced by patients who were provided your TVT-S;

x. The investigation, evaluation and determination as to whether there is a causal connection between the design of your TVT-S and any adverse event or injuries;

y. The substantive design and approval of package inserts, IFUs, and other labeling for your TVT-S (both U.S. and foreign), including the specific dates of use for each such items and any design changes thereto;

ii. The maintenance of Ethicon Inc.'s finances, budgets and expenditures with regard to design and development related to its TVT-S from the date first started developing its TVT-S until the present;

jj. The interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of your TVT-S, from the date Ethicon, Inc. first started developing TVT-S until the present;

kk. As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization;

z. The identity of the individuals involved the defendants' original decision to design, develop and manufacture the TVT-S;

aa. All medical assessments of the TVT-S as it relates to the design control and validation process;

bb. The specifics of all clinical, preclinical, and medical testing related to the TVT-S during the design and development stages;

cc. Animal Testing Records for Biocompatibility as part of the design of the product;

dd. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your TVT-S;

ee. The development and coordination of any pre-clinical studies, clinical trials and design testing regarding your TVT-S;

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. Two exemplar products for all products listed in "TVT-S" definition above.

3. Prototype meshes and tissue samples/pathology/histopathology slides of all pathology testing on TVT-S.

4. All documents concerning corporate, departmental, and employee organizational charts for your design and development department, product development or product cycle teams.

5. The following documents for the design and development of TVT-S, including but not limited to:

a. The Clinical Expert reports;

b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);

c. Operating Procedures for Failure Modes and Effects Analysis;

d. Operating Procedure for Device Design Safety Assessment;

e. Design history files;

f. Design and specifications of equipment used in the production of TVT-S;

g. Design and specifications of packaging used in the production of TVT-S;

h. Specifications regarding sanitization and sterilization of TVT-S, plant facilities and plant equipment;

i. Mesh Specifications;

j. Franchise procedure for medical device risk management plan;

k. Company procedure for medical device risk management plan;

l. Work Instruction for device risk management;

m. The Franchise procedure for the control and disposition of nonconforming product;

n. All company policies and procedures that apply to or relate to the Design History File;

o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;

p. Risk management plans and reports for TVT-S;

q. Members of product development team(s);

r. Operating procedures associated with a product development cycle;

s. TVT-S quality manual;

t. TVT-S quality plan;

u. Management responsibilities under a quality system;

v. Mesh product design review, design verification, process qualification and design transfer;

w. Mesh product device design requirements matrix;

x. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;

y. Mesh product validation test reports; and

z. Mesh product biocompatibility testing records;

6. All documents concerning your protocol or standard operating procedures (SOP) not listed in number 3 above for:

a. Your design and development department;

b. Your risk management department;

c. Your quality assurance department; and

d. Testing and Validation of TVT-S.